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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/303,040	04/30/1999	BARBARA J. WINSLOW	54957-B/JPW/	7815

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/303,040	WINSLOW ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *3/28/2005 & 7/23/2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-65 and 67-77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *37-65, 67-77* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The instant communication is responsive to the interview summary of March 28, 2005 and to the response received from applicants on July 23, 2004. Please note that the claims in the response of July 23, 2004 omitted claims 73 and 74. These claims have been accounted for in the instant communication.

The Examiner and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to examiner **Ulrike Winkler, Group Art Unit 1648.**

Claims 37-65 and 67-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rendered indefinite in that they only describe the composition by an arbitrary name. While the name itself may have some notion of activity of the protein, there is nothing in the claims that distinctly describes the feline CD28 protein, feline CD80 protein, feline CD86 protein or feline CTLA-4 protein and variants thereof. For example, others in the field may isolate the same protein and give it an entirely different name. Applicant should particularly point out and distinctly claim the "protein molecule and variant thereof" by claiming characteristics associated with the protein (e.g. activity, molecular weight, amino acid composition, sequence identifier, N-terminal sequence, etc.). Claiming a biochemical molecule by a particular name given to the protein by the various workers in the field fails to distinctly claim what that protein is and what the composition is made of.

Upon review and reconsideration of the instant invention it is noted that the claims should have been subjected to an Election/Restriction requirement. A new Election/Restriction requirement is set out below. The Office apologizes in advance for any inconvenience this may cause applicants.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 37*, 41, 48, 52, 53, 54, 56, 57, 58, 59, 76 and 77, drawn to a recombinant viral vector expressing one foreign nucleic acid structure, classified in class 435, subclass 320.1.

II. Claims 37*, 38, 42, 43, 44, 45, 46, 47, 49, 50, 51, 55, 69, 70, 73, 74 drawn to a recombinant viral vector expressing two foreign nucleic acid structures, classified in class 435, subclass 320.1.

III. Claims 37*, 39, 71, 72, drawn to a recombinant viral vector expressing three foreign nucleic acid structures, classified in class 435, subclass 320.1.

IV. Claims 37* and 40, drawn to a recombinant viral vector expressing four foreign nucleic acid structures, classified in class 435, subclass 320.1.

V. Claims 60, drawn to a vaccine comprising a mixture of a recombinant virus with an effective immunizing amount of a second immunogen, classified in class 424, subclass 184.1.

VI. Claims 61, 62 and 64, drawn to a method of enhancing an immune response by administering a recombinant virus, classified in class 424, subclass 9.2.

VII. Claims 63, and 65, drawn to a method of suppressing an immune response by administering a recombinant virus, classified in class 424, subclass 9.2.

VIII. Claims 67 and 68, drawn to a method of abrogating a tumor in a feline by administration of CD80, classified in class 435, subclass 7.23.

IX. Claims 67 and 68, drawn to a method of abrogating a tumor in a feline by administration of CD86, classified in class 435, subclass 7.23.

X. Claims 67 and 68, drawn to a method of abrogating a tumor in a feline by administration of a mixture of CD80 + CD86, classified in class 435, subclass 7.23.

For each of invention set I-VII above, restriction to one of the following is also required under 35 USC 121. If an invention set from the groups I-VII is elected then a further election of inventions (A)-(D) is also required.

(A). feline CD28 protein
(B). feline CD80 protein
(C). feline CD 86 protein
(D). feline CTLA-4 protein

For each of invention set I-X above, restriction to one of the following is also required under 35 USC 121. If an invention set from the groups I-X is elected then a further election of inventions (E)-(G) is also required.

(E). raccoonpox virus (claim 41)
(F). swinepoxvirus (claims 41, 76, 77)
(G). feline herpesvirus (claim 41)

For each of invention set II-IV above, restriction to one of the following is also required under 35 USC 121. If an invention set from the groups II-IV is elected then a further election of inventions (H)-(Z) is also required.

(H). rabies virus
(I). Chlamydia
(J). Toxoplasma gondii
(K). Dirofilaria immitis
(L). a flea
(M). a bacterial pathogen
(N). feline immunodeficiency virus
(O). feline panleukemia virus
(P). feline leukemia virus
(Q). feline peritonitis virus
(R). feline calicivirus

(S). feline reovirus type 3
(T). feline coronavirus
(U). feline syncytial virus
(V). feline sarcoma virus
(W). feline herpes virus
(X). feline borna disease virus
(Y). a feline parasite
(Z). a detectable marker (*E. coli* beta galactosidase)

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(D) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions (E)-(G) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to divergent molecules having different functions and effects. The polynucleotides can be used in hybridization assays as well as in expression methods for producing the polypeptides.

Inventions (H)-(Z) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to divergent molecules having different functions and effects. The polypeptides can be used as immunogens and thereby they would have different effects.

Groups I-V are compositions and are distinct from groups VI-X which are drawn to methods. Groups I-V are compositions and each is distinct from the other because they contain different materials. Group I comprises a recombinant vector having only one foreign nucleic acid inserted into the vector. Group II comprises a recombinant vector having two foreign nucleic acid structures inserted into the vector. Group III comprises a recombinant vector having three foreign nucleic acid structures inserted into the vector. Group IV comprises a recombinant vector having four foreign nucleic acid structures inserted into the vector. Group V is a mixture of a recombinant virus and a second immunogen. Though there may be overlap for these groups, the search for one group will not be coextensive with that of the other group.

Groups VI-X are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Groups VI is drawn to a method of enhancing the immune response of a subject by injecting a recombinant virus into the subject. Group VII is drawn to a method of suppressing the immune response when injected into a subject. Though there may be overlap between Group VI and VII the outcomes are not expected to be the same thus a search for one method will not overlap with the search for the other method. Group VIII is drawn to treating a tumor in a feline using a CD80 expressing recombinant vector. Group IX is drawn to treating a tumor in a feline using a a CD86 expressing vector. Group X is drawn to a method of suppressing a tumor in a feline using combination of CD80 and CD86. The method of Groups VII-X uses different steps from the other methods, thereby setting them apart.

Inventions VII-X are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require

the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination (CD80+CD86) does not rely solely on either subcombination for patentability as evidenced by both subcombination being within the combination. Additionally, the claim indicates that either subcombination CD80 or CD86 effectively function on their own.

Claim 37 link(s) inventions Groups I-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 37. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 37 link(s) inventions (E)-(G). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 37. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable

linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claim 44 link(s) inventions (H)-(Y). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 44. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Inventions I-V and VI-X are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the recombinant viruses can be used to produce proteins that can be used in diagnostic assays that are materially different processes than using the products as a vaccine or in treatment methods. Alternatively, the treatment methods can be practiced with materially different products such as chemotherapeutic agents.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/12/05